b.) Remarks

The Examiner notes that claims 3-5, 8-12 and 26-34 are withdrawn from prosecution as being drawn to a constructively non-elected invention. In response, solely in order to reduce the issues, those claims have been cancelled without prejudice or disclaimer.

Claims 16, 19-20, 23, 25, 35, 37, 39 and 41 stand rejected under 35 U.S.C. 102(b) as anticipated by Woodle (U.S. Patent No. 5,356,633). In support of the rejection, the Examiner states Woodle teaches multilamellar vesicles (MLVs) having a liposome size of 160 nm, that contain both steroidal and non-steroidal anti-inflammatory agents and the anticancer agent methotrexate. Woodle is said to teach both liposomes containing cholesterol and those containing no cholesterol (Table 3 and Example 7).

As noted, however, the lipids used for the preparation of Woodle's MLVs are PEG-DSPE, DPPC and DSPC. Therefore, Woodle does not teach or suggest a liposome preparation or a pharmaceutical composition having an average particle size of 120 nm to 500 nm, in which lipid(s) constituting the liposomes are selected from the group consisting of hydrogenated soybean phosphatidylcholine, distearoyl phosphatidylcholine and polyethylene glycol-modified phospholipid.

Claims 16, 19-20, 23, 25, 35, 37, 39 and 41 are also rejected under 35 U.S.C. 102(b) as being anticipated by Burke (U.S. Patent No. 5,552,156). Similar to Woodle, the Examiner states that Burke discloses MLVs and unilamellar vesicles containing the anti-cancer agent camptothecin. The lipids include DSPC. Burke also teaches liposomes containing no cholesterol in example 1-3.

Although Burke does not teach the size of the liposomes, the Examiner states such is interent. However, such sizes are not inherent. Inherency requires that the noted characteristic necessarily and always occur. Once the Examiner alleges inherency, the burden shifts to Applicant to show that the prior art does not inherently possess the recited feature of the claimed invention. In re King 801 F2d 1324, 1327 (Fed. Cir. 1986).

This burden has already been met. Comparative Example 5 provided in Applicants' November 20, 2003 Amendment clearly evidences that the particle size of liposomes prepared like Burke by being vortexed without sonication is >500 nm.

Claims 16, 19-20, 22-23, 25, 35-37, 39 and 41 are rejected under 35 U.S.C. 102(a) or (b) as anticipated by EP 0 850,646, of record, because the Examiner states EPO '646

> EP discloses liposome formulations containing indolocarbazole derivatives. The liposomes are made from hydrogenated phospholipids and PEG-DSPE (note abstract, page 4, Examples and claims). Although, EP does not explicitly state that the liposomes are multilamellar, according [sic] the examples (example 1), the lipid film is hydrated and vortexed and not sonicated. Therefore, formation of multilamellar vesicles with sizes more than 120 nm is implicit...[t]he examples in the reference show no addition of cholesterol...[Also, e]xamples (1 and 22) of EP shows that the preparation is passed through 0.4 micron filters (400 nm). It is logical therefore, to expect the sizes of the liposomes to be within the range claimed.

This rejection is respectfully traversed for several reason. First, at the outset, the preparation of the liposomes in examples 1 and 22 in the reference is passed through 0.4 micron filters (400 nm) 5 times, and then through 0.1 micron filters (100 nm)

10 times. Therefore, the average particle size of <100 nm is implicit. Second, in any event, EP '646 does not teach or suggest that the lipids constituting the liposomes are selected from the group consisting of hydrogenated soybean phosphatidylcholine, distearoyl phosphatidylcholine and polyethylene glycol-modified phospholipid, as in the present invention.

Claims 24 and 38 are rejected under 35 U.S.C. 103(a) as being obvious unpatentable over Woodle in optional view of Mauer, *BBA*, Vol. 1374 (1998) 9-20, of record. Woodle is relied upon as above, and the Examiner concludes that it would have been obvious to one of ordinary skill in the art that any desired drug could be encapsulated as shown by encapsulation of the antibiotic ciprofloxacin in Mauer. However, this combination of prior art does not address the deficiencies noted in Woodle, discussed previously.

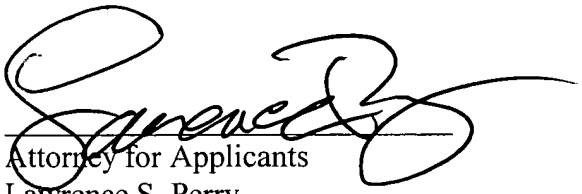
Claims 22 and 36 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Woodle cited above in combination with EP '646. As with claims 24 and 38, however, this rejection does not address the deficiencies of the references as noted.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 16, 19-20, 22-25, 35-39 and 42-48 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,



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